

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the adoption of New) NOTICE OF ADOPTION
Rules I through VI pertaining to the)
medical marijuana program)

TO: All Concerned Persons

1. On September 25, 2008, the Department of Public Health and Human Services published MAR Notice No. 37-452 pertaining to the public hearing on the proposed adoption of the above-stated rules at page 2027 of the 2008 Montana Administrative Register, Issue Number 18.

2. The department has adopted New Rule III (37.107.104), Rule IV (37.107.107), and Rule VI (37.107.109) as proposed.

3. The department will not be adopting New Rule V at this time.

4. The department has adopted the following rules as proposed with the following changes from the original proposal. Matter to be added is underlined. Matter to be deleted is interlined.

NEW RULE I (37.107.101) DEFINITIONS In addition to the terms defined in 50-46-102, MCA, the following definitions apply to this chapter:

(1) through (3) remain as proposed.

~~(4) "Attending physician" means a Doctor of Osteopathy or medical doctor who has established a bona fide physician/patient relationship with the applicant, is licensed under Title 37, chapter 3, MCA, and who, with respect to an applicant diagnosed with a debilitating medical condition:~~

~~(a) is primarily responsible for the medical care and treatment of the applicant;~~

~~(b) has reviewed the applicant's medical records at the request of the applicant;~~

~~(c) has conducted a thorough physical examination of the applicant;~~

~~(d) has provided or planned follow-up care; and~~

~~(e) has documented these activities in the applicant's medical record.~~

(5) through (7) remain as proposed but are renumbered (4) through (6).

AUTH: 50-46-210, MCA

IMP: 50-46-103, 50-46-210, MCA

NEW RULE II (37.107.103) REGISTRATION AND APPLICATION
PROCESS (1) through (5) remain as proposed.

(6) If the applicant wants to use a caregiver, a caregiver must be designated on the application. The caregiver must sign a statement agreeing to provide medical

marijuana as needed and available only to those qualifying patients who have designated on their application that individual as their caregiver.

(7) through (11) remain as proposed.

AUTH: 50-46-210, MCA

IMP: 50-46-103, 50-46-210, MCA

5. The department has thoroughly considered the comments and testimony received. A summary of the comments received and the department's responses are as follows:

COMMENT #1: Several comments were received supporting the proposed rule changes.

RESPONSE #1: The department thanks the commentors for their support.

COMMENT #2: I am concerned about product quality and use of pesticides and other substances used on the plants, which patients would then inhale along with the product. There should be requirements set forth to guard against this from occurring.

RESPONSE #2: The department runs the Medical Marijuana Program registry and has no authority to prescribe growing practices related to medical marijuana. Therefore, the comment is beyond the scope of the department's rule.

COMMENT #3: I would like the department to consider implementing a rating scale for caregivers. Patients should have something available to help them choose among available caregivers as to the caregivers' abilities to provide them with good service and a quality product.

RESPONSE #3: The department runs the Medical Marijuana Program registry and has no authority to recommend caregivers. Implementing a rating scale for caregivers would be comparable to having a licensing board recommend a licensee. It is the consumer's responsibility to educate themselves in order to receive good service and a quality product.

COMMENT #4: Caregivers are performing a safety sensitive function in producing this product. As such, caregivers should not be allowed to use the product themselves. A patient of the Medical Marijuana Program should not be a caregiver for another. This should be made clear in the rulemaking process.

RESPONSE #4: The department disagrees. A caregiver may also be a qualifying patient if they meet the definition of a "qualifying patient" and if they meet criteria enumerated in 50-46-103(2)(a) through (e), MCA.

COMMENT #5: The rules should include a process to allow a person to lodge a complaint or concern that a caregiver with a valid certificate may not be following the statutory provisions under the Medical Marijuana Act (Act).

RESPONSE #5: The department runs the Medical Marijuana Program registry and has no authority to run a clearinghouse for complaints and lacks the authority to enforce law violations.

COMMENT #6: I have concerns that there is a belief and an attitude among the community, particularly those who use marijuana, that the use of marijuana does not cause impairment when driving. The commentor elucidated the research on the issue and referred to several studies found on the subject.

RESPONSE #6: Section 50-46-205, MCA, prohibits any person to operate, navigate, or be in the actual physical control of any motor vehicle, aircraft, or motorboat while under the influence of marijuana. It is unnecessary to reiterate this prohibition in rule.

COMMENT #7: There is concern about the length of time it takes the department to make caregiver changes.

RESPONSE #7: The department is aware of the processing time for caregiver changes, but is currently meeting the statutory requirements for verifying applicant information and issuing registry identification cards. However, the increase in applicants and caregiver change requests is making this progressively more difficult. Therefore, the department is seeking legislative approval to hire an additional half-time employee to meet the statutory deadlines and provide quality customer service to those individuals with debilitating medical conditions who benefit from the program.

COMMENT #8: It appears these proposed rules restrict the physician-patient relationship in ways that were not contemplated in the Act itself. By reading, the definition of physician is changing to "attending physician" and requires that the doctor take a greater role that is contained in the Act by adding Rule I(4)(a) through (e) (37.107.101). Specifically, that doctor now must have performed a "thorough physical examination" and "documented these activities in the applicant's medical record". In another section, the rules add the requirement that all that be performed within the last three months, all that has to happen each time a patient renews his or her application yearly. The commentor gets the sense the department is further trying to specify that the physician be a primary care physician, although it is not clear, that seems to be the implication of the requirement that there also be "planned follow-up care".

RESPONSE #8: The department agrees and has deleted the definition of "attending physician" in proposed Rule I(4)(a) through (e) (37.107.101).

COMMENT #9: I propose the addition of Rule I(4)(f) (37.107.101) requiring the attending physicians to complete training on the pharmacology et cetera of marijuana as follows:

"(4)(f) has successfully completed a training program approved by the department in the pharmacology, pharmacokinetics, and pharmacotherapeutics of marijuana. This program will include the adverse effects of using marijuana and the danger to public safety if a person under the influence of marijuana operates a vehicle on a public highway and/or performs any safety sensitive function in a private or public workplace."

RESPONSE #9: The department declines to add the suggested language to proposed Rule I(4)(f) (37.107.101). The requested language is beyond the scope of the rule amendments and would require a statutory inclusion into the Medical Marijuana Act. Additionally, marijuana is classified as a Schedule I drug by the FDA. It is not part of a pharmacopeia that can be prescribed by any practitioner. Finally, it would be discriminatory. The department does not require that sort of training of physicians concerning any other medications or treatments which they prescribe or recommend.

COMMENT #10: I proposed the addition of Rule I(8) (37.107.101) to the Definitions rule as follows:

"(8) "Safety sensitive function" means performing a task which could result in serious injury or death if the performer experienced a momentary lack of concentration. Examples would include, but are not limited to, handling hazardous materials, administering medications, working with electrical, hydraulic, nuclear, or combustible power."

RESPONSE #10: The department declines the addition to proposed Rule I(8) (37.107.101) for the definition term "safety sensitive function". The term is not found or used anywhere in the rule. Consequently, there is no context to the definition as it relates to the published rule.

COMMENT #11: We propose the addition to Rule II(2)(e) (37.107.103) requiring the attending physician to attest that the applicant has been informed about side effects of medical marijuana. Registrants should not be allowed to:

- operate a vehicle; use medical marijuana in the presence of a minor;
- use in a public place;
- and physician should inform each registrant it's addictive/may cause significant social and occupational dysfunction.

RESPONSE #11: The department disagrees. These suggestions exceed the scope of proposed Rule II (37.107.103) and would require statutory change to the Act and are of questionable constitutionality.

COMMENT #12: I propose an additional subsection to Rule II(2) (37.107.103) that would require attending physician to complete form 20-1900 "Driver Medical Evaluation" form and to mail it to the Department of Justice Motor Vehicle Division.

RESPONSE #12: The proposed request for an additional subsection to Rule II(2) (37.107.103) exceeds the scope of proposed Rule II (37.107.103) amendments and would require a statutory change to the Act.

COMMENT #13: We propose the additional subsection to Rule II (37.107.103) that would require a caregiver to provide the following:

(a) Copy of a negative drug test performed on specimen of hair from the body of the caregiver by a laboratory approved by the department.

(b) Specimens must be collected by a certified collector approved by the department. Specimens will be tested for THC, amphetamines, opiates, cocaine, PCP, and/or metabolites of these drugs.

(c) Evidence that the caregiver is included in a random testing program administered by either the department or a third-party administrator approved by the department. This program will test at least 50% of the enrolled caregivers during each quarter. If a caregiver is notified of selection the caregiver must report to an approved collector within 48 hours.

(d) Costs for drug testing required by this program will be paid by the caregiver.

(e) Test results will be reported to the department. If a drug test is positive for any illegal drug the caregiver's registry identification card will be revoked and the caregiver will never be eligible to have the card reinstated.

(f) A signed and dated form stating that the caregiver is familiar with the information listed in this rule.

RESPONSE #13: This proposed additional subsection to Rule II (37.107.103) is outside of the scope of the proposed rule amendments and would require a statutory change to the Act.

COMMENT #14: While we support the department's proposal to Rule II(6) (37.107.103), they are concerned that the rule's wording implies that registered caregivers are required at all times to keep patients supplied with their legal medicine. Unfortunately, under the law's severe restrictions on the number of plants that can be grown for a patient, this is not always possible. The commentors would thus be more comfortable if, in this rule's second sentence, words such as "as needed and available" were to be inserted between "marijuana" and "only".

RESPONSE #14: The department agrees and has amended Rule II(6) (37.107.103) accordingly.

COMMENT #15: There may be many individuals who have expert gardening skills and could grow a quality product who would be excluded as caregivers due to a nonrelated felony. We understand and share concerns about individuals who may have been found guilty of criminal offenses against a person, and it should be

grounds for preventing such a person from being a caregiver. We also have concerns about people who have not been found guilty of a felony who may still pose a threat to patients due to violent acts against a person but who were not convicted of a felony. Any offense against a person should be grounds to prevent a person from being a caregiver. There needs to be a method in place to guard against such a person becoming a caregiver.

RESPONSE #15: The Act restricts the department from issuing a registry identification card to a proposed caregiver who has previously been convicted of a felony drug offense. Nonrelated felony convictions do not prohibit an individual from being a caregiver. The Act does not address convictions or nonconvictions related to criminal acts against a person. Therefore, the department is not authorized to address these concerns in rule. This would require a statutory change to the Act.

COMMENT #16: I have had trouble growing regular plants in my area of Montana. If there is an individual with a felony charge against them, which is not one that does not pose a danger to the patient, and they possess the skills needed to grow and provide a quality product to patients, they should be allowed to be a caregiver.

RESPONSE #16: This comment is beyond the scope of proposed Rule II (37.107.103). Please see response to comment #15.

COMMENT #17: I propose an addition to proposed Rule III (37.107.104), Invalidation or Revocation of Registry Identification Card, in which a law enforcement officer who performs a lawful traffic stop may require a registered patient to submit to a serum drug test if they are operating a motor vehicle on a public road.

RESPONSE #17: This comment exceeds the scope of proposed Rule III (37.107.104) and would require a statutory change to the Act.

COMMENT #18: I propose an addition to proposed Rule III (37.107.104) that states when law enforcement performs a lawful stop they may require caregiver to submit to hair drug testing. Any positive result would revoke the caregiver card immediately and would render the caregiver to be ineligible for a card reinstatement.

RESPONSE #18: This comment exceeds the scope of proposed Rule III (37.107.104) and would require a statutory change to the Act.

COMMENT #19: Section 50-46-201, MCA, states that "a qualifying patient or caregiver...may not be arrested, prosecuted or penalized in any manner...for the medical use or assisting in the medical use of marijuana." We know what the intent of the legislature is. However, the way it was written unfortunately might convey to the caregiver that they are also protected by law to use marijuana even though it says "medical use". It seems to me that the wording of the law needs to clearly separate who is protected for medical use of marijuana and who is protected for cultivating or providing (caregiving) marijuana to the patient.

RESPONSE #19: The department thanks the commentors for their comment. This comment exceeds the scope of proposed Rule I (37.107.101) and would require a statutory change to the Act.

COMMENT #20 I think the fact that proposed Rule V allows for "extenuating circumstances" gives a great deal of latitude for the department to decide when things are getting abused or too confused and should be there. The commentor is a little concerned that it may limit competition between caregivers, and requests the department try and avoid that. It seems reasonable that there are going to be some unreliable types out there who want to be caregivers and who do not ultimately meet a patient's reasonable expectations for whatever reason. The caregiver out there that can actually meet that need should not be restricted from doing business with patients because of the errors of the lousy previous caregivers. As long as that situation can be taken into account as an "extenuating circumstance", then the commentor would have no objection.

RESPONSE #20 Due to comments and suggestions received regarding limiting caregiver changes, the department will not adopt proposed Rule V at this time.

/s/ Lisa A. Swanson
Rule Reviewer

/s/ Anna Whiting Sorrell
Anna Whiting Sorrell, Director
Public Health and Human Services

Certified to the Secretary of State March 2, 2009.